

REMARKS

Claims 12- 14 were withdrawn from examination in the response to restriction requirement filed by Applicants on July 25, 2003.

The Applicants have canceled claims 1-11 and 15-19 without prejudice to their right to pursue future examination of the claims.

The Applicants present new claims 20 -24. Support for the new claims may be found in the old claims and also in the Specification on page 2 in paragraph 5 and in Example 2 on page 11 in paragraph 1. Entry of this amendment is respectfully requested.

The Examiner has rejected claims 1-6 and 15-19 under 35 U.S.C. § 103(a) over Bay et al., WO 00/59863, Leone-Bay et al. '536, or Leone-Bay et al. '647 taken with GB 2295966 or WO 0057857, and Purkaystha. The Applicants disagree with the Examiner and respectfully request that the Examiner withdraw the rejection of the claims based on the following reasons. The Applicants have created a solid pharmaceutical composition which displays greatly enhanced oral bioavailability over other oral pharmaceutical compositions. The Applicants have provided comparative examples which show the greatly enhanced bioavailability of the present invention. The Applicants have determined that the use of the delivery agent 5 CNAC with crospovidone or povidone provides more than five-fold increase in the oral bioavailability of a pharmacologically active agent. This showing is provided in Example 2 in the Applicants' Specification which identifies greatly enhanced pharmacokinetic parameters of a formulation of the invention using crospovidone (Comparative Example A) versus formulations employing another frequently used excipient, carboxymethylcellulose sodium, in place of crospovidone. Example 2 shows that the blood level uptake of the active agent, salmon calcitonin, is increased more than five-fold by using a composition of the claimed invention that contains crospovidone versus compositions that contain the same active agent and delivery agent but which do not use crospovidone. This showing is evidenced by the difference in the blood level Cmax and Area Under the Curve (AUC) values in Rhesus monkeys after oral dosing of the compositions of the invention versus the comparative compositions.

None of the references cited by the Examiner, nor any prior art, has shown that crospovidone or povidone in combination with the delivery agents and active agents claimed by the Applicants can be employed to make a solid pharmaceutical composition having improved oral bioavailability.

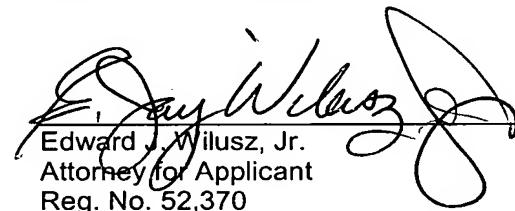
Based on the foregoing the Applicants respectfully request that the Examiner withdraw the rejection of claims 1-6 and 15-19 under 35 U.S.C. § 103(a) over Bay et al., WO 00/59863, Leone-Bay et al. '536, or Leone-Bay et al. '647 taken with GB 2295966 or WO 0057857, and Purkaystha.

The Applicants believe that the application is now in condition for allowance and respectfully request early notice to that effect.

If the Examiner deems that additional fees are properly assessable in the case or that certain fees should be refunded, the Examiner is authorized to charge or credit such fees to Deposit Account No. 19-0134 in the name of Novartis Corporation.

If it will advance prosecution of the Application the Examiner is urged to contact the Applicants' undersigned counsel at the telephone number listed below.

Respectfully submitted,



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